Boston Scientific

SYNTAX Analysis Finds Treatment With TAXUS® Express2™ Stents More Cost Effective Than Bypass Surgery in Many Patients With Complex Coronary Artery Disease

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NATICK, Mass. and ORLANDO, Fla., March 28 /PRNewswire-FirstCall/ -- Boston Scientific Corporation today announced results from an analysis of economic and quality of life outcomes, based on one-year data from its landmark SYNTAX trial. The results found that while the overall cost effectiveness of percutaneous coronary intervention (PCI) versus coronary artery bypass graft (CABG) surgery varied according to patient characteristics, PCI was more cost effective than CABG in patients with low or moderate coronary lesion complexity. CABG was more cost effective than PCI in those with the most complex disease. The results also found that both PCI and CABG improved several quality of life measures.

Analysis of the data was presented by David J. Cohen, M.D., M.Sc., Director of Cardiovascular Research at Saint-Luke's Mid America Heart Institute and Professor of Medicine at the University of Missouri (both in Kansas City), at the American College of Cardiology (ACC) Annual Scientific Sessions.

"This analysis demonstrates that the cost effectiveness of PCI versus CABG depends largely on patient characteristics, notably lesion complexity as defined by the SYNTAX Score," said Dr. Cohen. "The data on quality of life will be helpful to physicians and patients as they consider an appropriate course of treatment. Long-term results will be essential to providing more definitive guidelines for treating these complex coronary patients, and five-year follow up is planned for all patients in the SYNTAX trial."

"Previously published SYNTAX data showed no difference in safety and efficacy outcomes between PCI and CABG in patients with low or moderate lesion complexity," said Keith D. Dawkins, M.D., Associate Chief Medical Officer of Boston Scientific. "Today's finding that PCI was more cost effective than CABG at one year in these same patient groups supports PCI as a rational alternative treatment option for these patients."

SYNTAX is the first randomized, controlled clinical trial to compare PCI using the TAXUS® Express2™ Paclitaxel-Eluting Coronary Stent System to CABG in patients with left main disease and/or significant narrowing of all three coronary arteries (three-vessel disease). According to published guidelines, these patients are traditionally treated with CABG, and they have been excluded from most prior drug-eluting stent clinical trials. The goal of the SYNTAX trial is to explore whether it is safe and effective to treat some or all of these 'surgical' patients with PCI using the TAXUS Express2 stent.

The cost-effectiveness analysis compared the relative benefits in overall quality of life to the relative U.S. health care costs, for both PCI and CABG. In those patients with low or moderate lesion complexity, PCI was favored, providing more quality-adjusted life years and lower net medical costs than CABG. For patients with the most complex disease -- and in whom the increase in repeat revascularization for PCI versus CABG was greatest -- CABG provided slightly more quality-adjusted life years, with no significant difference in net medical costs at one year.

The results showed that both PCI and CABG demonstrated equivalent rates of "substantial improvement" in angina relief as compared to baseline at one, six and 12 months (57.6% PCI v. 58.3% CABG at 12 months) (p=statistically insignificant). The number of patients who reported being angina free was comparable for PCI and CABG at one month (64.4% v. 61.6%) and six months (68.5% v. 72.0%) (p=statistically insignificant for both), but was higher in the CABG group at 12 months (71.6% v. 76.3%) (p=0.05).

In addition, the study showed that total medical costs were $5,693 lower for PCI than for CABG for the initial hospitalization ($27,560 for PCI v. $33,254 for CABG) (p<0.001), and remained $3,590 lower for PCI than CABG through 12-month follow-up ($35,991 for PCI v. $39,581 for CABG) (p=<0.001). The narrowing in the cost difference between hospital discharge and 12-month follow-up was the result of the cost of repeat revascularization procedures and higher long-term costs of anti-platelet medication in the PCI group.

It has been previously reported that one-year SYNTAX data demonstrated comparable safety for the two treatment groups, with no overall statistically significant differences between PCI and CABG in rates of death or myocardial infarction (MI, or heart attack), although there were significantly more strokes in patients treated with CABG. The rate of repeat revascularization was significantly higher in the PCI group (13.7 % v. 5.9%), although most procedures in the PCI group were repeat PCI, with only a small percentage requiring CABG. However, because of the increased need for repeat procedures, the overall 12-month MACCE (Major Adverse

Cardiovascular or Cerebrovascular Event rate, including all-cause death, stroke, MI and repeat revascularization) was significantly higher for PCI.

An earlier analysis of the SYNTAX trial outcomes based on the SYNTAX Score also demonstrated that among patients with a SYNTAX Score in the upper tercile -- those with the most complex disease -- there was a significant increase in MACCE for PCI patients compared with CABG patients, driven by the expected higher rate of revascularization in the PCI group. PCI and CABG patients whose scores fell into the lower or intermediate terciles of complexity had similar rates of MACCE at 12 months. The SYNTAX Score characterizes coronary anatomy based on lesion frequency, complexity and location, and assigns a score to each patient.

The safety and effectiveness of the TAXUS Express2 Stent System have not been established in patients with left main or three-vessel disease.

Boston Scientific is a worldwide developer, manufacturer and marketer of medical devices whose products are used in a broad range of interventional medical specialties. For more information, please visit: www.bostonscientific.com.

Cautionary Statement Regarding Forward-Looking Statements

This press release contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934. Forward-looking statements may be identified by words like "anticipate," "expect," "project," "believe," "plan," "estimate," "intend" and similar words. These forward-looking statements are based on our beliefs, assumptions and estimates using information available to us at the time and are not intended to be guarantees of future events or performance. These forward-looking statements include, among other things, statements regarding clinical trials, regulatory approvals, competitive offerings and product performance. If our underlying assumptions turn out to be incorrect, or if certain risks or uncertainties materialize, actual results could vary materially from the expectations and projections expressed or implied by our forward-looking statements. These factors, in some cases, have affected and in the future (together with other factors) could affect our ability to implement our business strategy and may cause actual results to differ materially from those contemplated by the statements expressed in this press release. As a result, readers are cautioned not to place undue reliance on any of our forward-looking statements.

Factors that may cause such differences include, among other things: future economic, competitive, reimbursement and regulatory conditions; new product introductions; demographic trends; intellectual property; litigation; financial market conditions; and, future business decisions made by us and our competitors. All of these factors are difficult or impossible to predict accurately and many of them are beyond our control. For a further list and description of these and other important risks and uncertainties that may affect our future operations, see Part I, Item 1A- Risk Factors in our most recent Annual Report on Form 10-K filed with the Securities and Exchange Commission, which we may update in Part II, Item 1A - Risk Factors in Quarterly Reports on Form 10-Q we have filed or will file thereafter. We disclaim any intention or obligation to publicly update or revise any forward-looking statements to reflect any change in our expectations or in events, conditions, or circumstances on which those expectations may be based, or that may affect the likelihood that actual results will differ from those contained in the forward-looking statements. This cautionary statement is applicable to all forward-looking statements contained in this document.

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